Remarks

Claims 1-17 and 37-44 are pending in the subject application. Applicants acknowledge that claims 8-17 and 37 have been withdrawn from further consideration as being drawn to a non-elected invention. By this Amendment, Applicants have amended claims 1, 6, 39, 42, and 43 and canceled claim 44. Support for the amendments can be found throughout the subject specification and in the claims as originally filed. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 1-17 and 37-43 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

As an initial matter, Applicants gratefully acknowledge the Examiner's indication that claim 38 is objected to for depending upon a rejected base claim and is free of the prior art.

Claims 1-7 and 38-44 are objected to because of informalities. In accordance with the Examiner's suggestion, Applicants have deleted the phrase "as set forth in Table 2" from the claims. Accordingly, reconsideration and withdrawal of this objection is respectfully requested.

Claims 1-7 and 39-44 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully assert that there is adequate written description in the subject specification to convey to the ordinarily skilled artisan that they had possession of the claimed invention. The Office Action indicates that the subject specification fails to describe the common attributes or characteristics that identify members of the genus. Applicants respectfully traverse this rejection.

It is noted that the test for an adequate written description has been stated in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. It is respectfully

submitted that Applicant has met this test given the teachings of the specification and the scope of the claims.

The Federal Circuit has also addressed the written description requirement in the context of DNA-related inventions. See *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 63 U.S.P.Q.2d 1609 (Fed. Cir. 2002). The *Enzo* court adopted the standard that "the written description requirement can be met by 'showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ... *i.e.*, complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.'" *Enzo* at 1324, 63 U.S.P.Q.2d at 1613. The court in *Enzo* adopted its standard from the Patent Office's Written Description Examination Guidelines. See 296 F.3d at 1324, 63 U.S.P.Q.2d at 1613 (citing the Guidelines) and the guidelines are recognized to apply to proteins as well as DNA molecules.

The Office Action argues that adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required (citing to *Fiers v. Revel*). The Office Action also argues that the specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." Finally, the Office Action argues that the Federal Circuit has indicated that a generic statement that defines a genus by only its functional activity does not provide adequate written description of the genus (citing to the Federal Circuit's decision in *The Regents of the University of California v. Eli Lilly*.

Applicants respectfully submit that the Patent Office's reliance on *Lilly* and *Fiers* in support of its position that the claimed invention fails the written description requirement with respect to fragments of SEQ ID NO: 3 is misplaced. In cases such as *Fiers* and *Eli Lilly*, the patent specifications at issue did not identify the sequence (structure) of any embodiment of DNA claimed therein. *See Eli Lilly,* 119 F.3d at 1567-68 (affirming a judgment that the claim requiring cDNA encoding human insulin was invalid for failing to provide an adequate written description where the specification described the human insulin A and B chain amino acid sequences encoded by the cDNA, but did not provide the nucleotide sequence for the cDNA itself); *Fiers,* 984 F.2d at 1167-68, 1170-71 (finding the written description insufficient where the patent claimed purified DNA

encoding human fibroblast interferon-beta polypeptide, but the specification only disclosed a bare reference to DNA and suggested a process to sequence it). Applicants respectfully point out that Table 2 provides actual written description of various polypeptide fragments of SEQ ID NO: 3. Thus, Applicants respectfully submit that the as-filed specification clearly teaches and provides written description for polypeptide fragments of between 16 and 88 consecutive or contiguous amino acids of SEQ ID NO: 3, and provides a precise definition of such polypeptides by structure and biological activity. Under both the *Eli Lilly* and *Fiers* analysis, the as-filed specification of this application is sufficient to satisfy the written description requirement.

To the extent that this rejection is predicated on the use of the transitional term "comprising", Applicants also respectfully traverse the rejection. Applicants note that the term "comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim (*see Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997). Applicants have provided the sequence of SEQ ID NO: 3 and have also delincated the various fragments within the scope of the claims in Table 2. While it is recognized that the claims cover proteins that include the recited sequences joined with additional sequences (elements), the open nature of the transitional phrase "comprising" does not mean that applicants were not in possession of such polypeptides. For example, the specification teaches the fusion of the claimed polypeptides, and fragments thereof, to various elements to form variant polypeptides containing heterologous tags, polypeptides joined by linker elements, multimeric polypeptides, or elements that provide adjuvant activity (see, for example paragraphs 24-28 and 30-31 of the as-filed specification). As the Patent Office is aware, the use of the transitional term "comprising" does not allow for internal alterations (*e.g.*, insertions or deletions) of the sequence set forth in SEQ ID NO: 3 (or fragments thereof comprising between 16 and 88 consecutive amino acids), but instead only allows for the addition of elements at either end of the sequence. The fact that the claimed polypeptide fragment can have additional elements attached to either, or both, ends does not in any fashion alter the fact that the as-filed specification provides adequate written description of polypeptide fragments comprising a recited span of contiguous/consecutive amino acids joined to heterologous elements, such as linkers or adjuvant

proteins. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claims 1-7, 39, and 44 are rejected under 35 U.S.C. § 102(b) as anticipated by Knowles *et al.* (U.S. Patent No. 5,798,219). The Office Action states that the sequence disclosed by Knowles *et al.* is 100% identical to amino acids 17-31 of SEQ ID NO: 3. This corresponds to a span of 15 consecutive/contiguous amino acids. Applicants respectfully assert that the Knowles *et al.* reference does not anticipate the claimed invention as the claims now recite a span of between 16 and 88 consecutive amino acids of SEQ ID NO: 3. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested.

Claims 1-7, 39, and 42-44 are rejected under 35 U.S.C. § 103(a) as obvious over Knowles *et al.* (U.S. Patent No. 5,978,219) in view of Vaughan *et al.* (U.S. Patent No. 4,654,419). Applicants respectfully assert that the claimed invention is not obvious over the cited references, regardless of whether the references are taken alone or in combination. The Office Action states that the Vaughan *et al.* patent teaches constructing multimers containing a plurality of repeating units and that such molecules have the advantages of increased antigenicity and increased immunogenicity. The Office Action further states that it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have taken the molecule having greater than 5 (*e.g.*, a span of 15 consecutive amino acids as taught by the Knowles *et al.* patent) contiguous amino acids of the instantly claimed SEQ ID NO: 3 as taught by Knowles *et al.* and generated a multimer as taught by Vaughan *et al.* As discussed above, the claims have been amended to recite a fragment of SEQ ID NO: 3 that comprises 16 to 88 contiguous/consecutive amino acids of SEQ ID NO: 3. Knowles *et al.* clearly do not teach such a polypeptide. As the Patent Office is aware, all the claim limitations must be taught or suggested by the prior art in order to establish the *prima facie* obviousness of a claimed invention. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). Thus, it is respectfully submitted that the combination of Knowles *et al.* and Vaughn *et al.* fail to render the presently claimed invention obvious as the combination of references fails to teach each and every limitation of the claimed invention. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) is respectfully requested.

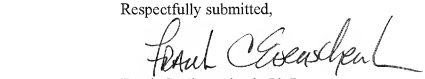
It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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